

Cooperative Agreement
Between
New York City Department of Health and Mental Hygiene
And
Dispensing Partner
Regarding Mass Prophylaxis at an
Inpatient Psychiatric Facility

COOPERATIVE AGREEMENT (“Agreement”), dated as of the day on which this Agreement is either electronically or manually signed on behalf of the Inpatient Psychiatric Facility, is entered into by and between the New York City Department of Health and Mental Hygiene (“DOHMH”), having offices at 42-09 28th Street, Long Island City, New York 11101, and the individual or entity, which is signing this Agreement, who or which is the licensed operator of a licensed inpatient psychiatric facility (the “Dispensing Partner”).

R E C I T A L S

WHEREAS, pursuant to the New York City Charter, DOHMH promotes and protects the public health in New York City;

WHEREAS, pursuant to the Citywide Incident Management System, DOHMH is a “primary” or lead agency in New York City during a public health emergency;

WHEREAS, certain public health emergencies necessitate rapid access to medical countermeasures, such as antibiotics, antivirals, antitoxins, and/or vaccines, (the “Medical Countermeasures”) in order to protect the health of individuals in New York City;

WHEREAS, DOHMH seeks to enroll New York City’s inpatient psychiatric facilities in its Public Health Emergency Response Network (“PHERN”) Auxiliary Distribution Program (“ADP”) to augment Medical Countermeasures dispensing capabilities during certain public health emergencies;

WHEREAS, Dispensing Partner is licensed to operate and as of the date of this Agreement, operates a New York State inpatient psychiatric facility situated within New York City;

WHEREAS, Dispensing Partner seeks to partner with DOHMH to facilitate rapid access to appropriate Medical Countermeasures for its residents and employees during certain public health emergencies;

WHEREAS, during certain public health emergencies, DOHMH intends to activate its PHERN ADP, whereby it will transfer a pre-determined quantity of Medical Countermeasures to Dispensing Partner as needed and appropriate in accordance with the priorities of DOHMH;

WHEREAS, section 564A(e) of the Federal Food, Drug, and Cosmetic Act (“FD&C Act”), allows the U.S. Federal Food and Drug Administration (“FDA”) to issue Emergency Dispensing Orders to allow emergency dispensing (including mass dispensing at a point of dispensing (POD)) of Medical Countermeasures during an actual chemical, biological, radiological or nuclear (“CBRN”) emergency, without requiring an individual prescription for each recipient of the Medical Countermeasure(s), the FDA has issued such orders for the use of doxycycline and ciprofloxacin, and the FDA may issue additional such orders in the future; and

WHEREAS, the FDA has delegated to the federal Centers for Disease Control and Prevention (“CDC”) its authority to create and issue emergency use instructions (“EUIs,” also referred to as fact sheets for recipients of an Medical Countermeasure and for health care professionals) about FDA-approved conditions of use for such Medical Countermeasures before or during a CBRN event, and the FDA and the CDC entered into a Memorandum of Understanding to establish a framework for the agencies’ coordination in support of CDC’s use of its delegated authority to develop and issue such EUIs; and

WHEREAS, Dispensing Partner shall, upon receipt of Medical Countermeasures from DOHMH, dispense such Medical Countermeasures in strict accordance with this Agreement, incident specific instructions from DOHMH to be issued at the time of the public health emergency, any applicable Emergency Use Authorizations (“EUAs”) and Emergency Dispensing Orders issued by the FDA, EUIs issued by the CDC, and other applicable law(s) and regulations implemented thereunder now or hereafter in effect;

NOW THEREFORE, DOHMH and Dispensing Partner agree as follows:

I. Terms and Conditions

Pursuant to this Agreement, the parties shall have preliminary readiness obligations to fulfill in preparation for certain public health emergencies (“Routine” obligations), as well as obligations to fulfill during such public health emergencies and recovery thereafter (the “Emergency and Recovery” obligations).

- A. For its **Routine** obligations, Dispensing Partner shall:
1. Register online and provide requested information via the PHERN ADP website;
 2. Designate Primary and Secondary Points of Contact, both of whom shall be notified if DOHMH activates the PHERN ADP in response to a public health emergency and who shall make arrangements to receive emergency deliveries of Medical Countermeasures within four hours of such notification, 24 hours a day, seven days a week. In addition, the primary emergency Point of Contact shall be the individual responsible for ensuring ongoing administrative compliance with the terms of this Agreement, including all routine and emergency obligations set forth herein.
 3. On a quarterly basis, ensure that the Primary Point of Contact responds to the email from DOHMH described in Section I.C.2., reviews the registration information and

provides updated information as warranted, to include the anticipated maximum number of employees and residents expected to receive Medical Countermeasures during the course of a public health emergency requiring mass prophylaxis, as well as delivery address information;

4. Update changes to Primary and Secondary Point of Contact information via the PHERN ADP website within five business days; and
5. Participate fully in DOHMH-sponsored exercises testing the parties' ability to undertake the emergency activities specified herein, including but not limited to quarterly telephone notification drills testing DOHMH's ability to notify Dispensing Partner, via Primary and Secondary Points of Contact, of a PHERN ADP activation.

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B. For its **Emergency and Recovery** obligations, Dispensing Partner shall:

1. Within four hours of notification, be prepared to accept delivery of Medical Countermeasures, and stand ready to receive same until such time as delivery is made;
2. During the time that the Medical Countermeasures remain in the possession of Dispensing Partner, ensure that Medical Countermeasures supplied by DOHMH will be handled, stored, and maintained in accordance with applicable FDA requirements and specifications provided by the manufacturer, except to the extent that such requirements are modified by a relevant EUA or other authority;
3. Dispense and/or administer Medical Countermeasures to its employees and facility residents only, and only to the extent that such employees and residents are individuals or members of a “priority group” designated by DOHMH as eligible to receive Medical Countermeasures in incident specific guidance issued at the time of the public health emergency;
4. Ensure that it dispenses and/or administers Medical Countermeasures in accordance with its own mass dispensing plan, this Agreement, incident specific guidance from DOHMH to be issued at the time of the public health emergency, any relevant EUAs issued by the FDA, and other applicable law(s), and such regulations as may have been or may be promulgated under such applicable law(s);
5. Dispense/administer Medical Countermeasures to its entire employee and resident population within the time parameters established by DOHMH using incident specific guidance issued at the time of the public health emergency. It is understood and agreed by Dispensing Partner that the time parameter within which this obligation must be completed may be as rapid as 24 hours after receipt of Medical Countermeasures by Dispensing Partner;
6. Dispense and/or otherwise administer Medical Countermeasures in accordance with this Agreement without fee, charge or other remuneration in any form, for either the dispensing and/or other administering of such Medical Countermeasures or for associated costs incurred for medical supplies or other fees, including, without limitation, insurance reimbursement, supplies for the administration (such as syringes, gauze, Band-Aids, alcohol prep pads, containers, packaging, and the like), and the indirect cost of administration, unless specifically authorized to do so in writing by DOHMH. Under no circumstances shall Dispensing Partner directly or indirectly seek any payment from any individual for the dispensing and/or administration of the Medical Countermeasures, unless specifically authorized to do so in writing by DOHMH;

7. Provide DOHMH educational materials (*e.g.*, fact sheets) to all individuals receiving Medical Countermeasures in accordance with incident specific instructions issued by DOHMH at the time of the public health emergency;
8. Maintain (i) complete and accurate records concerning the receipt, handling, dispensing, administration, and inventory of Medical Countermeasures; (ii) all completed screening forms for which Medical Countermeasures are dispensed/administered; (iii) any additional information deemed necessary by DOHMH, and provide the foregoing data to DOHMH in a timely manner according to incident specific instructions at the time of the public health emergency and in accordance with applicable local, state and federal requirements;
9. Prepare incident reports, including adverse event reports, as appropriate, and supply copies of same to DOHMH upon request;
10. Secure and store any unused Medical Countermeasures in accordance with applicable state and federal law and incident specific guidance from DOHMH until such time as DOHMH, or its duly authorized designee, retrieves such Medical Countermeasures or otherwise provides instructions regarding disposition; and
11. If requested by DOHMH, and under DOHMH guidance, prepare and submit a timely after-action report (“AAR”) to DOHMH identifying the accomplishments and shortfalls of mass dispensing operations and related activity.

C. For its **Routine** obligations, DOHMH shall:

1. Maintain the PHERN ADP registry and use the information provided by Dispensing Partner to facilitate distribution of Medical Countermeasures during certain public health emergencies as needed and appropriate based upon the priorities of DOHMH;
2. On a quarterly basis, send an auditing e-mail to Dispensing Partner’s Primary Point of Contact containing instructions to verify and update Dispensing Partner’s information in the PHERN ADP as referenced in Section I.A.3.;
3. Provide pre-event planning and technical assistance to Dispensing Partner, including screening forms, and additional guidance as appropriate; and
4. Conduct routine exercises testing the parties’ ability to undertake the emergency activities specified herein, including but not limited to quarterly telephone notification drills testing DOHMH’s ability to notify Dispensing Partner of a PHERN ADP activation.

D. For its **Emergency and Recovery** obligations, DOHMH shall:

1. Provide timely notification of a public health emergency necessitating mass prophylaxis to Dispensing Partner;

2. Provide to Dispensing Partner incident specific guidance pertaining to dispensing and/or administering Medical Countermeasures, which may include screening forms, applicable EUAs and fact sheets regarding Medical Countermeasures, as well as reporting obligations and instructions for disposing of unused Medical Countermeasures;
3. Provide emergency Point of Contact information enabling Dispensing Partner to contact appropriate DOHMH personnel as needed in connection with this Agreement and the public health emergency;
4. Provide consultation and assistance as needed and available during the public health emergency to Dispensing Partner;
5. Facilitate collection or disposal of unused medications as well as copies of all medical documentation from Dispensing Partner in a coordinated, reasonable and timely manner;
6. Provide after-action guidance and consultation to Dispensing Partner; and
7. Not charge Dispensing Partner for any Medical Countermeasures supplied in accordance with this Agreement.

E. The Parties further agree to:

1. Protect the confidentiality of its residents' and employees' information with respect to the performance of the activities to be performed hereunder in accordance with the Health Insurance Portability and Accountability Act (HIPAA), where applicable, and any applicable state and local law, except as may be modified pursuant to executive order or other authority based upon a public health emergency.
2. Proceed with the activities set forth in this Agreement only at the request and direction of DOHMH. Individuals from DOHMH Office of Emergency Preparedness and Response and their designees are authorized to work with Dispensing Partner to initiate and advance the activities specified herein.
3. Participate voluntarily. It is understood that Dispensing Partner's participation in the PHERN ADP is voluntary, and prior to notification of a public health emergency, it may elect not to receive Medical Countermeasures for use in mass prophylaxis dispensing operations by opting out of this Agreement pursuant to Section III herein. If, however, Dispensing Partner receives notification from DOHMH of a public health emergency and it has not previously terminated this Agreement pursuant to Section III, Dispensing Partner shall accept delivery of Medical Countermeasures and proceed with dispensing/administering same to its employees and residents in accordance with this Agreement.

II. Term and Renewal

- A. The term of this Agreement shall be five years from the date on which it is signed on behalf of Dispensing Partner.
- B. The initial term of this Agreement may be extended sequentially for additional five year renewal terms by written agreement of both parties, signed and delivered in the same manner as this Agreement may be signed and delivered.

III. Termination

- A. This Agreement may be terminated by either party upon sixty (60) days prior notice in writing to the other party, except that this Agreement may not be terminated by Dispensing Partner during the course of a public health emergency in which Dispensing Partner has been notified that delivery of Medical Countermeasures to Dispensing Partner is imminent.
- B. If Dispensing Partner fails to comply with any obligation set forth herein, such failure will be deemed a material breach of this Agreement. If DOHMH determines that Dispensing Partner is in breach of this Agreement it may take one or more of the following actions:
 - 1. Ask Dispensing Partner for assurances that it will immediately initiate curative action to rectify the breach;
 - 2. Require Dispensing Partner to immediately return all or part of the unused Medical Countermeasures;
 - 3. Terminate this Agreement immediately and without 60 days prior written notice; and/or
 - 4. In addition to any other legal remedy it may have, seek an injunction or fraud indictment against Dispensing Partner.
- C. If Dispensing Partner fails to provide the required assurances as specified in III.B.1. above within the time specified by DOHMH or fails to initiate curative action within the time period specified by DOHMH, such failure will be deemed a material breach of this Agreement.
- D. If DOHMH terminates this Agreement, any remaining and unused Medical Countermeasures supplied by DOHMH will be promptly returned by Dispensing Partner to DOHMH in a manner specified by DOHMH, or shall be otherwise disposed of as may be directed by DOHMH.

IV. Amendments

This Agreement may be amended by a mutual agreement signed on behalf of both parties in the manner in which this Agreement may be signed at any time.

V. Liability

- A. The parties acknowledge that the Federal Public Readiness and Emergency Preparedness (“PREP”) Act, as addressed in 42 U.S. Code, Section 247d - 6d may provide immunity from suit and liability under Federal and State law with respect to claims of loss (except only willful misconduct) incurred from the administration to, or the use by, an individual of a covered countermeasure used during a period declared by the Secretary of the U.S. Department of Health and Human Services (HHS) to be a National State of Public Health Emergency. For additional information on the PREP Act, including the declarations issued by the Secretary of HHS invoking the Act’s protections, see: <http://www.phe.gov/preparedness/legal/prepact/pages/default.aspx>
- B. For information concerning emergency use authorizations issued by the FDA and their relationship to the PREP Act’s protections, see: <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm>
- C. Notwithstanding any other term of this Agreement, in no event shall New York City be liable to Dispensing Partner for special, indirect, incidental, exemplary, consequential (including, but not limited to, loss of profits) or punitive damages arising out of, or in connection with, the performance of this Agreement (even if New York City has been apprised of, or has foreseen the possibility of such damages).

VI. Emergency Dispensing Orders and Emergency Use Instructions

- A. The CDC has issued EUIs for the Medical Countermeasure use of doxycycline and ciprofloxacin as anthrax post-exposure prophylaxis (PEP). These EUIs and Doxycycline Preparation Instructions provide information on how to use these antibiotics during an anthrax (*Bacillus anthracis*) emergency, should such an event occur, and can be found at <https://www.cdc.gov/anthrax/public-health/eui-antibiotics.html>.
- B. It is understood by Dispensing Partner that the above referenced EUIs are issued by the CDC, and it is agreed that the Dispensing Partner will be responsible for accessing the current documents at the above link and complying with such orders, fact sheets, and doxycycline preparation instructions, all in accordance with DOHMH instructions.

VII. Effect

This Agreement does not supersede any contrary laws, rules or policies of either party.

VIII. DOHMH Administrative Point of Contact

The DOHMH administrative Point of Contact is the Countermeasures Special Projects Manager, who is responsible for ensuring compliance with this Agreement on an ongoing basis, unless

DOHMH sends a notice to Dispensing Partner in the same manner as this Agreement was delivered to DOHMH in which a replacement Point of Contact is designated by DOHMH.

Director, Clinical Planning Unit
NYC DOHMH
Attn: Bureau of Emergency Field Operation: CN-22E
42-09 28th Street
Long Island City, New York 11101-4132
Email Address: phernadp@health.nyc.gov

[NO FURTHER TEXT ON THIS PAGE—SIGNATURE PAGE FOLLOWS]

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IX. Execution of this Agreement

This Agreement is deemed signed by an authorized signatory on behalf of DOHMH upon Dispensing Partner signifying its agreement through its electronic signature or upon receipt by DOHMH of this Agreement, manually and duly signed by an authorized signatory for Dispensing Partner. Detailed instructions for the execution of this Agreement using either the Manual or Electronic process are provided in the Registration Instructions above.

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